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VI 510(k) Summary

Description

The Aspect Medical Systems, Inc. EEG Monitors, Models A-1000 and A-1050 with the processed parameter BIS, (hereafter referred to as the Aspect EEG Monitors with BIS) are microprocessor-based, up to 4 channel EEG monitors designed for use in the OR, ICU and for clinical research.

They acquire and display real-time EEG waveforms, as well as process the real time EEG data using digital signal processing techniques including the Fast Fourier Transform technique, and display the processed EEG data in several different formats. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

The system configuration includes a monitor, digital signal converter (DSC), optional printer, cables and electrodes.

The EEG Monitors with BIS conform to UL 544, CSA 22.2 no. 125 Risk Class 3, IEC 601-1. They also meet electromagnetic interference specifications outlined in IEC 801-2,3,4,5.

The Aspect EEG Monitors with BIS consist of two main components:

1) Monitor
2) Digital Signal Converter (DSC) - 4 channel maximum

A-1000 - 2,4 channel DSC
A-1050 - up to 2 channel DSC

Monitors

The monitors are microprocessor-based, and provide signal processing and display capabilities, displaying up to 4 channels of real time (i.e. "raw") EEG data as well as computing and displaying processed EEG parameters (examples of some processed parameters are listed below). They also display trend plots of processed EEG parameters in real time.

The front panel is configured with a large display screen, an index display board composed of a numeric index display and an alphanumeric index label display. There are a number of soft and hard keys, such as Set-up, Print, Alarm Limits, Trend, EEG, CSA+, DSA+, Review and Event.

The monitors contain the processors for processing the EEG data, calculating the variables and displaying the waveforms and variables.

The monitors consists of a PC-based CPU, an IPU and an FPU. The latter two are Digital Signal Processing subsystems for EEG processing.

DSCs

The Digital Signal Converters (DSCs) are electrically isolated, low noise, high gain amplifiers that also filter and digitize up to four (4) channels of EEG waveform data in either a bipolar or referential montage.

An overcurrent detector circuit monitors current to the DSCs. If the current exceeds the expected value, the power is shut off to the DSCs by the hardware, and the IPU is notified.

The DSCs are connected to the monitor by a flexible monitor interface cable.

Processed Parameters

There are a number of processed parameters which include the following:

Compressed Spectral Array (CSA), Density Spectral Array (DSA), Suppression Ratio(SR), Spectral Edge Frequency (SEF), Signal Quality Index (SQI) and the Bispectral Index (BIS).

Indications for Use

The Aspect EEG Monitors with BIS are intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The Bispectral Index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Reference:

Glass P, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index (BIS) Monitoring Allows Faster Emergence and Improved Recovery From Propofol/Alfentanil/N2O Anesthesia. In preparation for Anesthesiology.

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